REMARKS

I. Elections/Restrictions

Applicants' election with traverse of Group I was acknowledged, but the restriction requirement was deemed to be proper and made final. Office Action, p. 2. Applicants continue to traverse the requirement for all the reasons set forth in the Response and Amendment Under 37 C.F.R. § 1.111, filed on April 7, 2006, incorporated herein by reference. Applicants reserve all their rights to pursue the subject matter of the non-elected claims in this or any related applications.

II. Specification Is amended

Two informalities were identified in the specification and Applicants were requested to address these informalities. *Id.* at p. 3. Applicants amended the spedification at pages 26 and 8, in accordance with the Examiner's helpful suggestions, to address such informalities.

The specification was also objected to for the alleged inconsistency with claim 20. *Id.* Applicants' amendment of claim 20 overcomes this inconsistency.

III. Rejections Under 35 USC § 112

Claims 2-33 and 68 were rejected under 35 USC § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter regarded by Applicants as their invention. Several different bases were cited for this assertion.

It was alleged that claims 2-33 and 68 are vague and indefinite because it is "unclear if applicant is referring to the device of claim 1 or some other device," and an amendment "to – the device of claim 1 --" was recommended. Office Action, p. 4.

Applicants respectfully disagree. It is clear that the language of claims 2-33 and 68, "A device according to claim 1 ..." refers to the device of the preceding claim 1. Nonetheless, in the interest of expediting prosecution, Applicants amended these claims, as suggested in the Office Action. Applicants respectfully submit that the Amendment does not narrow the scope of the claims, which are entitled to their full scope of coverage afforded them prior to this amendment.

Claim 12 was alleged to be vague and indefinite because it is not clear if the porous material binds to proteins or if the immobilized analyte or analogue binds to proteins. Office Action, p. 4. Applicants respectfully point out that a person of ordinary skill in the art, reading claim 12 in view of specification, would readily understand that the porous material is a material which adsorbs the sample and permits it to migrate, e.g., see specification, pages 7-8. Such a person would also understand that the binding protein capacity of the porous material is a property of the porous material. The function of immobilized analyte or its analogue in the fourth zone is separate from the porous material's property. *Id.*

Claim 17 was rejected as indefinite and as an improper claim under 35 U.S.C. §101 because of its "use of CMO and/or HMS", but the absence of any steps involved in the method/process. It was also rejected as indefinite due to the use of acronyms, CMO and HMS. *Id.* The holdings of *Ex parte Dunki* 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. V. Brenner* 255. F. Supp. 131, 149 USPQ 475 (D.D.C. 1966), were relied upon for that assertion.

Applicants respectfully traverse and request withdrawal of these rejections. Applicants amended claim 17 to recite the full chemical names of the coupling agents.

Furthermore, coupling is performed using traditional procedures, well known in the art. *See* specification, page 19, lines 5-9.

A person of ordinary skill in the art would readily understand the metes and bounds of Applicants' claim 17. The *Dunki and Clinical Products* decisions fail to support the reasoning of the rejection. For example in *Clinical Products*, at issue were the definiteness under 35 U.S.C. §112, second paragraph, and statutory class of patentable subject matter under 35 U.S.C. §101 rejections of a claim directed to the "use of a sustained release therapeutic agent in the body of ephedrine adsorbed upon polystyrene sulphoric acid". The court reversed the indefiniteness rejection. The Section 101 rejection was upheld by the court based on the admission by the applicant that the adsorption compound, a drug resinate, formed by adsorbing ephedrine on cation exchange resins, was old.

In this application, Applicants have asserted and continue to assert that their claim 17 is novel and non-obvious in view of prior art. Since CMO-coupling and HMS-coupling are performed by conventional, art-recognized procedures, persons of ordinary skill in the art will be well aware how to accomplish the coupling. See specification, page 19, lines 5-9. Also, it is well established that procedures or information known in the art need not be included in a patent application. *Capon v. Eshhar,* 76 USPQ2d 1078 (Fed. Cir. 2005). (When the prior art includes the nucleotides in formation of the chimeric genes claimed in the appealed application, such information need not be determined afresh or included in the application to satisfy the written description requirement). Though *Capon's* holding is directed to written description, same reasoning should apply to the indefiniteness rejections.

Similarly in *Dunki*, the Board held that the claimed term "The use of a high carbon austenitic iron alloy ..." was an improper definition of a process. Nonetheless, this holding is inapposite to Applicants' claim 17, at least because that claim has no "use" recitation.

Claims 18 and 19 were rejected as indefinite because, allegedly, they fail to further limit the device of claim 1 since they "appear to be directed toward methods of making the device and do not positively recite limitations of the third zone ...". *Id.*, p. 5.

Applicants respectfully traverse this rejection. Claims 18 and 19 provide additional details of the properties of the third zone. Persons of ordinary skill in the art will readily understand the metes and bounds of these claims.

Claim 20 was also rejected as vague and indefinite allegedly because it is unclear if the 1-99% of the porous material is used for each zone or material used in relation to other zones, or if the percentage indicates overlapping of the zones.

Applicants' amendment of claim 20 overcomes this rejection.

The rejection of claim 27 as indefinite, based on the term "substantially consistent", is respectfully traversed. A person of ordinary skill in the art, familiar with Applicants' specification, would readily understand the scope of "substantially consistent and quantitative release of the non-immobilized molecule". The term at issue is similar to "about". It is well established that "about" is definite, even without the presence of its definition in the specification. See *B J Services Co. v. Halliburton Energy Services Inc.*, 67 USPQ2d 1692 (Fed. Cir. 2003)

IV. Claims Are Not Anticipated By Good

Claims 1-3, 5, 9-13, 20, 24, 25, 28, 30-33 and 68 were rejected for lack of novelty under 35 U.S.C. §102 in view of Good et al. (US 6,194,224) ("Good"). Applicants traverse this rejection.

Good discloses a device comprising a porous material membrane having a sample receiving zone, a reagent zone containing antibodies labeled with colloid gold particles, a test zone containing immobilized molecules of the specified analyte and a control

zone with a secondary antibody (i.e., an antibody to the labeled antibodies). If a detectable change is produced in the control zone, it is an indication that a sample is present. A detectable change is also produced in the detection zone when antibodies bind to the immobilized analyte. Coll. 3, ll. 4-21.

It was also stated that the device described by Good would retard the rate of migration of the sample and non-immobilized molecule. The reason for this assertion is that Good discloses the same device and the same pore size in the third zone that the applicant uses. Office Action, at p. 6.

Applicants traverse this assertion and the rejection.

Good merely states that the material used in the test zone is a microporeous, nitrocellulose material having a pore size of about 0.2 to about 0.5 microns in diameter. There is no suggestion that this material is capable of retarding the rate of migration of the sample and the non-immobilized molecule. In contrast, Applicants' porous material has a pore size in the range of 10-50 microus or greater, at least two orders of magnitude greater than that of Good. See, e.g., page 8, lines 22-30.

Furthermore, Good does not disclose a device comprising a calibration zone which includes an immobilized binding agent having an affinity for the labeled non-immobilized molecule capable of binding to the analyte to be assayed, wherein the amount of the analyte present in the sample is calculated from a signal obtained in the fourth zone and a signal obtained in the calibration zone.

At least for the reasons set forth above, Applicants respectfully submit that their claims 1-3, 5, 9-13, 20, 24, 25, 28, 30-33 and 68 are novel under 35 U.S.C. §102 in view of Good.

V. Claims 4, 6,7, 8, 14-19, 21-23, 26, 27 and 29 Are Not obvious over Good in view of Polzius, Schlipfenbacher, Davis, Lee, Henderson, Frushour, Robinson or Sundrehagen

Claims 4 and 6 were rejected as obvious over Good in view of Polzius et al. (U.S. Patent 6,130,097) ("Polzius") or Schlipfenbacher et al. (U.S. Patent 5,160,486) ("Schlipfenbacher"). It was alleged that Polzius teaches that it is known in the art to overlap zones on a test strip to provide for fluid contact of the zones. Schlipfenbacher was cited for its alleged teaching that overlapping zones are known in the art. It was concluded that it would have been obvious to combine Good with Polzius and Schlipfenbacher to obtain the device of claims 4 and 6, with overlapping zones.

The remaining claims rejected as obvious were similarly rejected by combining Good with other references as follows:

- Claims 7 and 8: over Good and Davis et al. (U.S. Patent 6,352,862) ("Davis") because allegedly Davis' teaching of several labeled specific binding reagents and multiple reagents, combined with Good would have made claims 7 and 8 obvious.

- Claims 14-16: over Good in view of Lee et al. (WO 02/04671) ("Lee") because allegedly Lee's disclosure of bovine serum albumin (BSA), combined with Good would have made obvious incorporating spacer molecules, including BSA, into Good's device, thereby rendering claims 14-16 obvious.

- Claim 17: over Good, in view of Lee, and Henderson et al. (U.S. 2004/0072248) ("Henderson") based on Henderson's alleged teaching of CMO conjugated to bovine serum albumin and to an estrogen, and used as a binding substance, immobilized on the surface of a test strip and used in assays. It was reasoned that it would have been obvious to incorporate CMO into Good's device (modified by Lee) to render prima facie obvious claims 14-16.

- Claims 18 and 19: over Good and Frushour et al. (U.S. 2003/0059951) ("Frushour") because Frushour's alleged teaching of the spatial separation zones on a test strip and the flow rate characteristics of the porous solid phase material can be selected to allow adequate reaction times in which the necessary specific binding can occur, and allow the labeled antibody in the labeled antibody zone to dissolve through the porous solid phase material.

  It was asserted that a person of ordinary skill in the art would have found it obvious to combine teachings of the two references, to achieve the device of Good with a changed length of the third zone.

- Claims 21-23: over Good in view of Robinson et al. (WO 95/16914) ("Robinson"), based on Robinson's alleged teaching of the calibration zones, in which a calibration reagent is immobilized and has biospecific affinity for the analyte or the binding partner of interest. Thus, according to the Office Action, it would have been obvious to one of ordinary skill in the art to include the use of a calibrator zone into the device of Good.

- Claims 26, 27 and 29: over Good in view of Sundrehagen (U.S. 6,716,641) ("Sundrehagen") based on Sundrehagen's alleged teaching of using reagents in zones of a test strip. According to the Office Action, Sundrehagen discloses that the use of the reagents prevents non-specific binding of the detector reagent and/or analyte.

Applicants do not concede that characterization of the references in the Office Action is correct. Even if, arguendo, it were correct, Applicants submit that, these rejections are misplaced as a matter of law.

At the outset, it is submitted that a proper obviousness rejection can be made only if there is some teaching, suggestion or motivation provided by the prior art, to combine

the teachings of the prior art. The Office Action failed to establish such teaching, suggestion or motivation in the prior art.

Furthermore, none of Good, Polzius, Schlipfenbacher, Davis, Lee, Henderson, Freshour or Sundrehagen ("secondary references") discloses or suggests the calibration zone as now recited in claim 1 (and thus in all the dependent claims included in the obviousness rejection). For at least this reason, the combination of Good with the secondary references (even if anguendo such a combination were proper), would not have suggested to a person of ordinary skill in the art the invention defined in claims 4, 6-8, 14-19, 21-23, 26, 27 and 29.

With respect to claims 21-23, the combination of Good and Robinson is improper at least because there is no suggestion or motivation in Good or Robinson to make the combination. The lack of suggestion or motivation to combine selected teachings of Good and Robinson is underscored by the fundamental differences between assays of these two disclosures. Good is directed to a competitive assay, while Robinson to a sandwich assay. Additionally, Robinson does not disclose or suggest a third zone capable of retarding the rate of migration as required by Applicants' claims. There is simply no suggestion or motivation in Good, Robinson or knowledge in the art to combine selected portions of these two fundamentally different disclosures to construct Applicants' claimed device. The motivation or suggestion might only have been provided by hindsight based on Applicants' disclosure. The use of hindsight in obviousness analysis is improper, as a matter of law.

VI. Request for Allowance

Applicants respectfully submit that all claims are in condition for allowance, an indication of which is solicited.

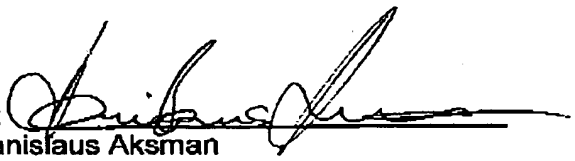
In the event any outstanding issues remain, Applicants would appreciate the courtesy of a telephone call to the undersigned Applicants' representative to resolve such issues in an expeditious manner and place the application in condition for allowance.

It is believed that no fees are due. However, in the event that any other fees are necessary, including extensions of time fees, the Director is hereby authorized to charge such fees or credit overpayment to our Deposit Account No. 50-2478.

Respectfully submitted,

ROBERTS MLOTKOWSKI & HOBBES P.C.

Dated: September 11, 2006

By: 
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